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Functional electrical stimulation associated with combined post-CABG training: a randomized clinical trial

Estimulação elétrica funcional associada ao treinamento combinado pós-CRM: ensaio clínico randomizado

Estimulación eléctrica funcional asociada con el entrenamiento combinado post-CABG: ensayo clínico aleatorizado

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ABSTRACT | The effects of adding functional electrical stimulation (FES) to short-term aerobic and resistance exercise (combined training) in patients undergoing coronary artery bypass graft (CABG) surgery have not yet been established. This study aims to evaluate the effect of adding FES to combined training on peripheral arterial flow, functional capacity and quality of life of post-CABG patients participating in a cardiac rehabilitation program – Phase II. This is a randomized, double-blind, clinical trial, composed of 17 patients (54.8±10.5 years old, 12 men) randomized or in an intervention group (IG, n=8,) submitted to FES in the quadriceps muscle associated with combined training, or in a sham group (SG, n=9), which performed the FES sham in association with the combined training. The evaluated outcomes were: peripheral arterial flow (ankle-brachial index), functional capacity (distance covered in the six-minute walk test – 6MWT) and quality of life (MacNew questionnaire). In the comparison between the groups, the increase in the ankle-brachial index (IG: 0.14±0.08mmHg vs. CG: 0.05±0.04mmHg; p=0.020) and the score of the global MacNew questionnaire (IG: 1.1±0.3 points vs. CG: 0.6±0.4 points; p=0.020) was higher in the IG. However, no difference was observed between the groups for the 6MWT (IG: 130.9±73.7m vs SG: 73.7±32.6m; p=0.072). The addition of FES, during a short period, potentiated the effects of aerobic and resistance exercise on peripheral arterial flow and quality of life in patients after CABG in Phase II of cardiac rehabilitation.

Keywords | Electrical stimulation; Cardiac Rehabilitation; Coronary Artery Bypass; Ankle-brachial Index; Quality of life.

RESUMO | Os efeitos da adição da estimulação elétrica funcional (EEF) ao treinamento aeróbico e resistido (treino combinado) de curto prazo em pacientes submetidos à cirurgia de revascularização do miocárdio (CRM) ainda não foram estabelecidos. O objetivo do presente estudo é avaliar o impacto da adição da EEF ao treino combinado no fluxo arterial periférico, na capacidade funcional e na qualidade de vida de pacientes pós-CRM participantes de um programa de reabilitação cardíaca – Fase II. Trata-se de um ensaio

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clínico randomizado, duplo cego, composto por 17 pacientes (54,8±10,5 anos, 12 homens) randomizados ou em grupo intervenção (GI, n=8,) submetido à EEF no músculo quadríceps associada ao treino combinado, ou em grupo *sham* (GS, n=9), que realizou a EEF *sham* em associação ao treino combinado. Os desfechos avaliados foram: fluxo arterial periférico (índice tornozelo-braquial), capacidade funcional (distância percorrida no teste de caminhada de seis minutos – DTC6M) e qualidade de vida (questionário MacNew). Na comparação entre os grupos, o aumento do índice tornozelo-braquial (GI: 0,14±0,08 mmHg vs. GC: 0,05±0,04 mmHg; p=0,020) e do escore do domínio global do questionário MacNew (GI: 1,1±0,3 pontos vs. GC: 0,6±0,4 pontos; p=0,020) foi maior no GI. Entretanto, não foi observada diferença entre os grupos para a DTC6M (GI: 130,9±73,7 m vs. GS: 73,7±32,6 m; p=0,072). A adição da EEF, durante curto período, potencializou os efeitos do exercício aeróbico e resistido sobre o fluxo arterial periférico e a qualidade de vida em pacientes pós CRM em Fase II da reabilitação cardíaca.

Descritores | Estimulação Elétrica; Reabilitação Cardíaca; Revascularização Miocárdica; Índice Tornozelo-Braço; Qualidade de Vida.

RESUMEN | Aún no se han establecido los efectos de agregar estimulación eléctrica funcional (EPS) cortoplacista al entrenamiento aeróbico y de resistencia (entrenamiento combinado) en pacientes sometidos a cirugía de injerto de derivación de las arterias coronarias (CABG). El objetivo del presente estudio fue evaluar el impacto de la adición de EPS al entrenamiento combinado sobre el flujo arterial periférico, la capacidad funcional y la calidad de vida de los pacientes post-CABG que participan en un programa de rehabilitación cardíaca de Fase II. Este es un ensayo clínico aleatorizado, doble ciego, compuesto por 17 pacientes (54,8±10,5 años, 12 hombres) aleatorizados en un grupo de intervención (GI, n=8) sometidos a EEF en el músculo cuádriceps asociado a entrenamiento combinado o en grupo simulado (GS, n=9), que realizó el simulacro de EEF en asociación con el entrenamiento combinado. Los resultados evaluados fueron: flujo arterial periférico (índice tobillo braquial), capacidad funcional (distancia recorrida en la prueba de caminata de seis minutos – 6MWT) y calidad de vida (cuestionario MacNew). Al comparar los grupos, el aumento del índice tobillo braquial (GI: 0,14±0,08 mmHg vs. GC: 0,05±0,04 mmHg; p=0,020) y la puntuación para el dominio global del cuestionario MacNew (GI: 1,1±0,3 puntos vs. GC: 0,6±0,4 puntos; p=0,020) fueron mayores en el GI. Sin embargo, no hubo diferencias entre los grupos en la 6MWT (GI: 130,9±73,7 m vs. GS: 73,7±32,6 m; p=0,072). La adición de EEF, durante un período corto, potenció los efectos del ejercicio aeróbico y de resistencia sobre el flujo arterial periférico y la calidad de vida en pacientes post-CABG en la Fase II de rehabilitación cardíaca.

Palabras clave | Estimulación Eléctrica; Rehabilitación Cardiaca; Revascularización Miocárdica; Índice Tobillo Braquial; Calidad de Vida.

INTRODUCTION

Cardiovascular diseases comprise the main causes of death and disability in Brazil and in the world, with coronary artery disease (CAD) responsible for 7.4 million of these deaths worldwide[1]. The treatment of CAD can be clinical or surgical, depending on the benefits of therapy considering the patient's clinical condition[2]. Coronary artery bypass graft (CABG) is effective in reducing symptoms and mortality in patients with CAD[2], but it has clinical and functional implications, which can even affect the musculoskeletal system[3].

According to previous studies, surgical stress causes dysregulation of protein metabolism due to postoperative hypercatabolism, which consequently induces the loss of muscle mass and the persistent reduction of muscle strength[4,5]. Such changes have been attributed to the systemic inflammatory response[4]. Furthermore, peripheral muscle impairment contributes to functional decline and reduced quality of life in patients undergoing cardiac surgery (CS)[3,4].

In this sense, evidence recommends the institution of cardiac rehabilitation (CR), whose typical strategy comprises aerobic and resistance exercises (combined training – CT). However, some patients are intolerant to low intensity exercise[6,7]. Additionally, in the face of changes in the musculoskeletal system after CS, there is a clear interest in the use of therapeutic resources that can minimize such effects, such as functional electrical stimulation (FES)[8].

FES comprises the application of intermittent and superficial stimuli to skeletal muscles, aiming to activate nerve branches and, thus, to stimulate visible contractions[9]. Systematic reviews have shown that the use of FES is able to promote an increase in strength and resistance of the quadriceps and functional capacity (FC) in patients with chronic obstructive pulmonary disease and an improvement in exercise capacity, quality of life, muscle

strength, endothelial function and depressive symptoms in patients with heart failure (HF)[10,11]. However, the literature is still scarce about the potential effect of FES associated with CR in post-CABG patients.

Within this context, the aim of the study was to evaluate the impact of adding FES to aerobic and resistance exercise (CT) on peripheral arterial flow, FC and quality of life of post-CABG patients participating in a CR – Phase II program.

METHODS

Study design

Double-blind randomized clinical trial, registered at ClinicalTrials.gov (Identifier: NCT03560713), carried out in the Cardiac Rehabilitation Program of the University Hospital of Santa Maria's (HUSM) Rehabilitation Unit of the Federal University of Santa Maria (UFSM), in Santa Maria (RS), Brazil, from April 2017 to June 2018. All participants signed a free and clarified consent form prior to inclusion in the study, as determined by resolution no. 466/12 of the National Health Council.

Participants

The eligibility criteria included patients undergoing CABG, aged between 50 and 70 years old, clinically stable, recruited from the waiting list for Phase II of the aforementioned hospital's CR and with the consent of the medical team to practice physical exercise. Subjects with clinical and hemodynamic instability, orthopedic problems, severe neurological problems, peripheral vascular changes in the lower limbs (deep vein thrombosis, thromboangiitis obliterans and obstructive arterial disease – OCAD) chronic obstructive pulmonary disease, cerebrovascular disease or who had the following contraindications to the use of FES: epidermal lesions at the application site, intolerance to electrical stimulation, changes in skin sensitivity or use of a pacemaker were excluded.

Randomization

The subjects included in the study were randomized into two groups: intervention group (IG), which performed FES in addition to the combined exercise (aerobic and resistance exercise), and the sham group (SG), submitted to FES sham in association with the CT. Block randomization was performed by a collaborator external to the study, through a random allocation order, using numbers 1 and 2 to designate the subjects of the IG and SG respectively, using the Random Number Generator software (Pro v2.00, Segobit, Issaquah, WA, USA).

In order to ensure the double-blind, patients were not informed about the allocation group and the FES was performed by a researcher who did not participate in the assessment of outcome measures.

Procedures

The patients underwent two days of evaluations, with a minimum interval of 48 hours between them. On the first day, anamnesis, physical examination and FC evaluation were performed. On the second day, the MacNew questionnaire was applied and the ankle-brachial index (ABI) was evaluated. All evaluations were carried out by previously trained evaluators.

Functional capacity (FC) assessment

FC was assessed using the six-minute walk test (6MWT) according to the recommendations of the American Thoracic Society (ATS)[12]. The distance covered was measured in meters and the values obtained were compared with the predicted equations of Enright and Sherrill[13].

Quality of life assessment

The Portuguese version, translated and adapted for cardiac subjects, of the MacNew Heart Disease Health-related Quality of Life Questionnaire (MacNew QLMI) was used to assess quality of life in an interview. To calculate the score obtained in the questionnaire, the mean scores of the physical, social and emotional categories were used. A higher score obtained in MacNew corresponds to a better quality of life[14].

Peripheral arterial flow assessment

Peripheral arterial flow was assessed by measuring the lower limb's (LL) ABI using the high-resolution Doppler ultrasonography (USG Doppler) method (EnVisor HD, Philips, Eindhoven, The Netherlands) with a 7 to 12MHz multifrequency linear transducer. The patient was placed in the supine position and the posterior brachial, feet and tibial arteries were included in the ABI assessment[15]. The assessment protocol was performed using an aneroid

sphygmomanometer (G-TECH/Premium) positioned just above the malleolus and inflated until the loss of arterial pulse, assessed with the aid of a stethoscope (Littmann Classic III 5803). After the ultrasound transducer, it was placed over the artery and the sphygmomanometer was deflated. Systolic blood pressure (SBP) of the upper limbs (UL) was also assessed.

The calculation used for the ABI comprised the division of the highest SBP value of the LL's muscles by the highest SBP value in the UL's muscles[15]. The ABI classification was based on the following values: 1.00 to 1.40 mmHg (normal), 0.91 to 0.99 mmHg (borderline) and indicative of OCAD less than 0.90[16].

Cardiac Rehabilitation Protocol (Phase II)

All patients were enrolled in the CR program (Phase II), whose physical training consisted of aerobic and resistance exercise, performed twice a week for 12 weeks, according to a protocol based on a previous study[17]. The aerobic exercises were performed on a treadmill (Inbramed, ATL – 10200, RS, BR), for 30 minutes, with the training intensity based on the heart rate (HR) obtained during the exercise test. The training HR was calculated through the difference between maximum HR and resting HR, with an intensity of 55-65% and a score of 4-6 on the modified Borg scale (ranging from 0 to 10)[17].

Resistance exercises for upper and lower limbs were performed with dumbbells and shin guards for approximately 20 minutes, with 3 sets of 10 repetitions per muscle group, with a rest interval of 30 seconds. Resistance exercise started with 40% of the maximum repetition test and continued until the patient reached 60%[8,17]. In a complementary way, exercises with elastic band (Thera-band®) were performed, whose resistance was estimated based on the color they presented. At the beginning and at the end of each session, 10 minutes of stretching were performed. Monitoring of vital signs was carried out constantly.

Functional electrical stimulation (FES) protocol

On the first day of intervention, the motor points of the femoral quadriceps were identified by scanning the area through an upper electrode positioned 4cm below the inguinal fold, while the lower electrode was placed above the patella on both lower limbs[18]. The FES was performed with the patient in the supine position, maintaining knee flexion at 60º. The application was carried out with a calibrated neuromuscular transcutaneous stimulator (Neurodyn High Volt, IBRAMED, Amparo, SP, Brazil) with 5×9cm rectangular self-adhesive electrodes, in which they were positioned at the motor points, with a frequency of 25Hz, duration of 200μs pulse, 5 seconds contraction time, 5 seconds rest time, 1 second rise and fall ramp and the highest possible current intensity to be tolerated by IG patient[18]. In the SG, the frequency used was 5Hz, which aimed not to cause a visible muscle contraction[18]. The intervention was carried out with a frequency of three weekly sessions for 12 weeks (duration of 30 minutes each session), with two weekly sessions being carried out before the CR program and, in the other session, the patient performed according to the appointment at the outpatient clinic. Monitoring of vital signs was carried out constantly.

Sample size calculation

The sample of this pilot study was used for sample inference of the randomized clinical trial, estimated to obtain a significance level of 5% ($p<0.05$) and power of 80% (GPower 3.1), considering a difference between the ABI means of 0.008±0.11mmHg and a necessary sample size of 9 patients in each group.

Statistical analysis

The data were analyzed using the Statistical Package for the Social Sciences software, version 20.0 (SPSS Inc., Chicago, IL, USA). The normality of the variables was assessed by the Shapiro-Wilk test. Continuous variables were presented as mean ± standard deviation and 95% confidence interval (95% CI), while categorical variables were presented in absolute frequencies and percentages. To compare the pre- and post-intragroup intervention moments, the paired Student's t-test was used. The comparison between groups was performed using the unpaired Student's t-test. For the purpose of statistical significance, $p<0.05$ was considered.

RESULTS

The flow diagram shows potentially eligible patients and those actually included in the present study (SG=9, IG=8) (Figure 1). During the study, no adverse events were observed in relation to the protocol. All patients completed the 36 FES sessions over the 12 weeks.

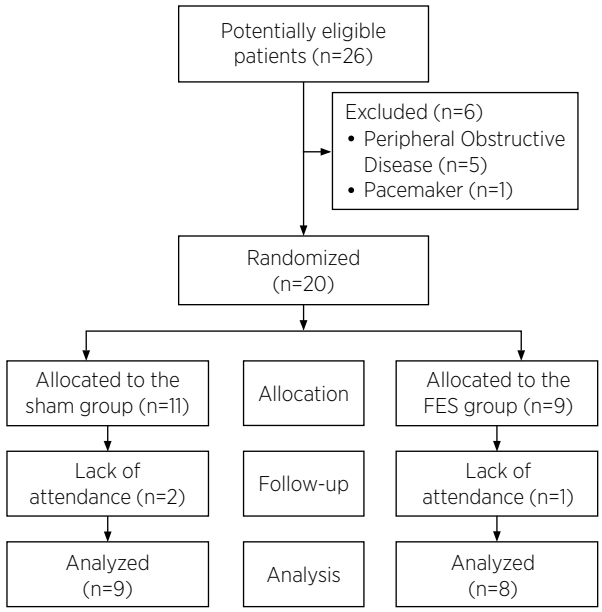

Figure 1. Study's flowchart

Table 1 shows the clinical and demographic characteristics of the patients included in the study.

Table 1. Clinical and demographic characteristics of patients

Variables	IG (n=8)	SG (n=9)
Age, years	51.6±12.4	57.7±7.2
Male sex, n (%)	5 (62.5)	5 (55.6)
BMI, Kg/m²	28.8±2.2	28.0±2.5
LVEF, %	59.1±14.9	60.4±12.8
DM, n (%)	5 (62.5)	5 (55.6)
SAH, n (%)	6 (75.0)	8 (88.9)
CR post-CABG start, days	35.8±2.1	38.4±1.7
Medications, n (%)		
NSAIDs	5 (62.5)	9 (100.0)
Antiplatelet	2 (25.0)	-
Statin	6 (75.0)	9 (100.0)
Diuretic	3 (37.5)	5 (55.6)
Anticoagulant	-	1 (11.1)
ACE inhibitors	6 (75.0)	1 (11.1)
Beta-blocker	5 (62.5)	7 (77.8)

Values expressed as mean and standard deviation; GS: sham group (FES sham + combined training); IG: intervention group (FES + combined training); BMI: body mass index; LVEF: left ventricular ejection fraction; DM: diabetes mellitus; SAH: systemic arterial hypertension; CR: cardiac rehabilitation; CABG: coronary artery bypass graft; NSAIDs: non-steroidal anti-inflammatory drugs; ACE inhibitors: angiotensin-converting enzyme inhibitors.

Figure 2 shows the increase in ABI observed in the intragroup comparison both in the IG (before: 1.05±0.05mmHg; after: 1.19±0.08mmHg; p=0.002) and in the SG (before: 1.04±0.05mmHg; after: 1.09±0.06mmHg; p=0.010) after the implementation of the protocol. In the comparison between the differences presented by the groups, in the moments before and after the protocol, a significant increase in the ABI was observed in favor of the IG (0.14±0.08mmHg vs. 0.05±0.04mmHg; p=0.020).

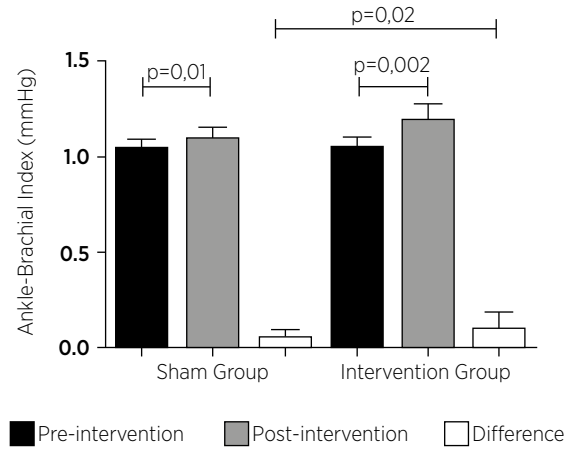

Figure 2. Comparison intra and between groups of peripheral arterial flow assessed using the ankle-brachial index at the evaluated moments

In the intragroup comparison, there was a significant increase in the 6MWT in the IG (130.9±73.7m, 95% CI 69.3 to 192.5) and in the SG (73.7±32.6m, 95% CI 48.7 to 98.8), but no significant difference was observed between the groups (57.2±27.1m, 95% CI -0.5 to 114.7). Considering the score for the global MacNew questionnaire, a significant increase was observed in the intragroup comparison both in the IG (1.1±0.3 points, 95% CI 0.8 to 1.3) and in the SG (0.6±0.4 points, 95% CI 0.2 to 0.9) (Table 2). In the comparison between the groups, a significant increase was observed in the score obtained in the MacNew questionnaire in favor of the IG after the protocol (0.5±0.2 points, 95% CI 0.09 to 0.9) (Table 2).

Table 2. Submaximal functional capacity and quality of life

	IG (n=8)			SG (n=9)			Comparison between groups	
Variables	Pre	Post	p	Pre	Post	p	Δ between groups	p
6MWT	414.7±49.8	545.6±60.8	0.002*ª	414.7±44.9	488.4±41.9	<0.001*ª	57.2±27.1	0.072ª
QOL	4.5±0.6	5.6±0.5	<0.001*ª	4.5±0.7	5.1±0.6	0.004*ª	0.5±0.2	0.020*ª

Values expressed as mean and standard deviation. IG: intervention group (FES + combined training); SG: sham group (FES sham + combined training; 6MWT: six-minute walk test; QOL: quality of life (score in the global MacNew questionnaire). Δ: variation; *: statistical significance p<0.05. ªStudent's T-Test.

DISCUSSION

In this randomized clinical trial, we investigated the effects of adding FES to CT (aerobic and resistance exercise) in patients post-CABG inserted in Phase II of CR. Our findings demonstrated that the addition of this therapeutic resource was able to potentiate the effects of CT on the increase in peripheral arterial flow and the improvement in quality of life. However, FES did not provide additional benefits in FC.

Our results are in line with previous studies, which demonstrated that the implementation of FES in the femoral quadriceps promoted an increase in endothelial function, measured through dilation mediated by the flow of the brachial artery, in patients with HF[18,19]. Thus, it is suggested that the beneficial changes induced by FES in peripheral hemodynamics and in the metabolic muscle state, as well as the reversal of physical deconditioning could explain the improvement in endothelial function[20]. However, it is important to mention that our study differs from those mentioned above in the fact that we recruit post-CABG patients; in addition, the measurement of peripheral arterial flow was performed using ABI, which has been considered a simple, reproducible, non-invasive and low-cost method[21]. It is noteworthy that the reduction in ABI is associated with the worsening of cardiac function, the severity of CAD, the increased risk of revascularization of the target lesion and of important adverse cardiac and cerebrovascular events[22].

Additionally, it is relevant to highlight that even using a short-term FES protocol, with a frequency of 3 times a week in association with CT, an increase in peripheral arterial flow was found. FES is known to induce muscle activity with increased oxygen uptake to the muscle, culminating in redistribution of blood flow, improvement of capillary perfusion and increased intramuscular blood flow[23]. Aerobic training also promotes an increase in peripheral arterial flow, due to the increase in cardiac output and muscle perfusion capacity, allowing greater oxygen release and, thus, minimizing flow resistance[24]. Similarly, resistance training can induce hemodynamic and structural adaptations, such as increased capacity for vasodilation of the endothelium and oxygen extraction by the muscle, which influence the musculoskeletal system[20,24]. Given the above, the possible explanation for the increase in peripheral arterial flow observed in our study may be related to the fact that FES was associated with CT. In contrast to findings demonstrated in previous studies[17,19], our study demonstrated that, after a 12-week period of FES associated with CT, there was an increase in peripheral arterial flow in post-CABG patients. This divergence can be explained by the protocol duration of only 6 weeks of FES without association with training in individuals with congestive heart failure (CHF)[17,19].

CABG provides clinically important improvement in quality of life in the late postoperative period. This premise was evidenced by a prospective study, demonstrating that one month after surgery, this outcome was still inadequate. However, satisfactory results were reported one year after the surgical procedure[25]. In this sense, investigating therapeutic resources that can improve quality of life in the short term is clinically relevant. According to our findings, FES can be one of these resources, as it was able to potentiate the effects of CT in improving the quality of life in the intervention group compared to the control group, after approximately 3 months after CABG. This result is in line with the findings of a pilot study conducted by Parissis et al.[19] in which 30 older adults with chronic HF demonstrated that FES, with a frequency of 25Hz, contraction time of 5s, rest time of 5s, intensity adjusted to the patient's tolerance limit, for 30 minutes, five times a week, for six weeks in the quadriceps and gastrocnemius muscles, was able to promote an improvement in quality of life.

FES was not able to provide additional benefits when associated with CT in the outcome related to exercise capacity. This finding is corroborated by a randomized clinical trial conducted in 20 post-CS patients, in which FES, with a frequency of 15Hz, contraction time of 5s, rest time of 10s, intensity at the limit of the patient's tolerance, for 40 minutes, twice a week, for eight weeks in the quadriceps muscle, caused an increase in the 6MWT intragroup (FES group and FES placebo group), but without any significant difference between the groups[9]. In contrast, Karavidas et al.[18] showed an increase in FC when investigating the effects of FES, with a frequency of 25Hz, contraction time of 5s, rest time of 5s, intensity tolerated by the patient, for 30 minutes, five times a week, for six weeks in the quadriceps and gastrocnemius muscles, in 30 patients with CHF and preserved left ventricular ejection fraction. It is inferred that such a divergent finding may be related to the fact that in the study previously mentioned, the use of FES was compared with placebo; in the present study, we compared the referred therapeutic resource with a co-intervention. It should be noted that the FES protocol used in our study was similar to that of Karavidas et al.[18], except for the muscle groups. It becomes relevant to consider that the efficacy of FES is dependent on the individual intrinsic

neuromuscular properties, which are superior to externally controllable factors (FES parameters) in determining the level of tension generated in the muscle[9]. It is worth noting that, despite the patients being instructed not to perform another form of exercise in their daily lives during the proposed intervention, it was not possible to control such variable, which could have caused implications for the outcome of FC.

This study has some limitations that must be considered. First, the absence of a control group composed of patients undergoing CABG, but who were not available to perform the proposed interventions, aiming to assess the process of natural recovery from the disease after the surgical procedure. In addition, it was not possible to perform an intention-to-treat analysis. Future studies with a larger sample size and longer follow-up could reinforce our findings, especially in relation to the outcome of FC.

Although there are limitations, our findings are relevant to clinical practice, as they provide a new perspective on the use of FES as a complement to physical training, being a low-cost resource and easy insertion in Phase II CR programs.

CONCLUSION

The present randomized clinical trial demonstrated that the addition of FES, even if conducted for a relatively short period and with reduced weekly frequency, was able to potentiate the effects of CT on peripheral arterial flow and quality of life in post-CABG patients inserted in the Phase II of the RC. Our findings also ratify the use of FES as a therapeutic intervention complementary to physical training, being a safe, low-cost resource with good adherence.

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